

**REMARKS**

Claims 1-18 are pending in the application. Claims 1-18 stand rejected as described below.

Claim 1 has been amended to recite that Applicant's guide wire has a first proximal end and a second distal end (with at least one interferometric guidance system coupled thereto), and that Applicant's guide wire distal end comprises at least one stationary fiber of said interferometric guidance system. No new matter is presented by this amending in that support for this amending is provided for example at pages 2-4 of the specification and the drawings. Claim 12 has been similarly amended. No new matter is presented by this amending in that support is provided in the specification for example at pages 2-4 and the drawings. Claim 14 has been similarly amended. No new matter is presented by this amending in that support is provided for example at pages 2-4 of the specification and the drawings.

Illustratively, Applicant's independent claim 1 reads: Apparatus configured to guide a guide wire through body tissue, said apparatus comprising a guide wire having a first proximal end and second distal end with at least one interferometric guidance system coupled thereto, said guide wire distal end comprising at least one stationary fiber of said interferometric guidance system, said interferometric guidance system configured for generating interference information from body tissue, wherein said interferometric system comprises a circuit for generating Doppler shift information configured to detect neovascular flow through the tissue by revealing relative changes in blood flow velocity at the guide wire distal end.

Claims 1-4 and 7-11 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Tearney et al. This rejection is respectfully traversed along with the Examiner's reasoning.

Tearney et al. describes an imaging system as whereas the claimed invention is an apparatus configured for guiding a guide wire, having a first proximal end and a second distal

end, with the guide wire's distal end comprising at least one stationary fiber, with at least one interferometric guidance system coupled to the guide wire's distal end. Applicants submit that Tearney et al. does not teach or suggest Applicants' guidance apparatus, but rather Tearney et al. discloses an apparatus for imaging. Applicants' claimed guide wire is not taught or suggested in Tearney et al. Applicants' apparatus is patentably distinct over Tearney et al. Tearney et al fails to teach or suggest a system for guiding a guide wire with the optical fiber comprising an interferometric system comprising a circuit for generating Doppler shift information configured to detect neovascular flow through the tissue using a guide wire where the distal end comprises at least one stationary fiber. More particularly Applicant points out that Applicants' Claim 1 has been amended to additionally recite Applicants' guide wire with an optical fiber forming its distal end. This claimed feature is not taught or suggested in Tearney et al.

Applicants' feature of having an optical fiber forming the distal end enables a user using Applicant's guidance system to advantageously look at where the guide wire is going rather than looking at a side view. By eliminating the optical system and window described in Tearney et al., Applicants' claimed invention allows the guide wire to be made simpler and smaller since mirrors, lens , and scanning systems are not needed in Applicants' invention. Tearney et al. describes a stationary fiber within the device to transmit light to an optical system where it is transmitted through a lens, a beam director through a window. (Refer to US 6,143,003, column 12, lines 28-39 and Figure 12.) There is no suggestion or motivation provided in Tearney et al. to modify Tearney et al. in any way. In particular, there is no suggestion in Tearney et al. of what modifications to make to provide Applicants' claimed invention.

Thus, the rejection of Claim 1 over Tearney et al. is overcome and should be withdrawn. While Tearney et al. mentions imaging, Applicants respectfully submit that Tearney et al. fails to teach or suggest a guidance system claimed by Applicants in particular having Applicants' guide wire.

Claims 2-4 and 7-11 depend on Claim 1 directly or indirectly when the recitations of Claims 2-4 and 7-11 are combined with the recitations of Claim 1, it is seen that Claims 2-4

and 7-11 are likewise patentable. Thus the rejection of Claims 2-4 and 7-11 is also overcome and should be withdrawn.

Claims 14 and 18 stand rejected under 35 USC 102(e) as being anticipated by Izatt et al. This rejection is traversed in its entirety.

Izatt et al. describes a method for generating a velocity-indicating, tomographic image of a sample in an optical coherence tomography system includes the steps of (a) acquiring cross-correlation data from the interferometer; (b) generating a grayscale image from the cross-correlation data indicative of a depth-dependent positions of scatterers in the sample; (c) processing the cross-correlation data to produce a velocity value and location of a moving scatterer in the sample; (d) assigning a color to the velocity value; and (f) merging the color into the grayscale image, at a point in the grayscale image indicative of the moving scatterer's location, to produce a velocity-indicating, tomographic image.

Independent Claim 14 recites: A method to determine neovascular flow through tissue in a vessel, said method comprising using an apparatus configured to guide a guide wire through body tissue, said apparatus comprising a guide wire having a first proximal end and second distal end with at least one interferometric guidance system coupled thereto, said guide wire distal end comprising at least one stationary optical fiber of said interferometric guidance system, said interferometric system configured to examine the vessel and to perform a Doppler shift analysis on frequencies of interference peaks generated by the interferometric system examining the vessel to determine the velocity of blood.

Claims 2-4 and 7-11 depend on Claim 1 directly or indirectly when the recitations of Claims 2-4 and 7-11 are combined with the recitations of Claim 1, it is seen that Claims 2-4 and 7-11 are likewise patentable. Thus the rejection of Claims 2-4 and 7-11 is also overcome and should be withdrawn.

Izatt et al. fails to teach or suggest Applicants' claimed invention in that Izatt et al. fails to disclose: A method to determine neovascular flow through tissue in a vessel, said method comprising using an apparatus configured to guide a guide wire through body tissue, said apparatus comprising a guide wire having a first proximal end and second distal end with

at least one interferometric guidance system coupled thereto a guide wire, said guide wire distal end comprises at least one stationary optical fiber of said interferometric guidance system said interferometric system employed to examine the vessel and comprising performing perform a Doppler shift analysis on frequencies of interference peaks generated by the interferometric system examining the vessel to determine the velocity of blood. More specifically, Izatt et al. fails to teach and suggest Applicants' guide wire having a first proximal end and a second distal end with at least one interferometric system coupled to the guide wire, and the guide wire distal end comprising at least one stationary fiber. Moreover even if Izatt et al. were somehow modified Applicants' claimed invention would not result in that Applicants' claimed feature of a guide wire with the distal end of a guide wire comprising at least one stationary fiber of an interferometric system is not taught nor suggested by Izatt et al. Accordingly, independent Claim 14 is patentable over Izatt et al.

Claim 18 depends directly on Claim 14. When the recitation of Claim 18 is considered in combination with the recitation of Claim 14, Applicants submit that Claim 18 is likewise patentable over Izatt et al. Thus the rejection is overcome and should be withdrawn.

Claims 5, 6, 12 and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Tearney et al. in view of Peterson et al. This rejection is respectfully traversed in its entirety along with its reasoning.

Tearney et al. is described above. Peterson et al. (U.S. Patent No. 5,549,114) describes an apparatus for performing Doppler blood flow studies wherein processing circuitry includes a frequency-to-voltage converter. Peterson et al. does not teach or suggest Applicants' claimed invention in particular Applicants' apparatus comprising a guide having a distal end comprising at least one stationary fiber of an interferometric system and configured to detect neovascular flow in tissue. Thus the claimed invention is patentably distinct over Peterson et al. as the above discussion shows.

Applicants' Claim 1 has been shown to be patentable over Tearney et al. Claim 6 is dependent on Claim 5 which in turn is dependent on Claim 2 which in turn is dependent on

Claim 1. When the recitations of dependent Claims 5 and 6 are considered in combination with the recitation of Claim 2 and in turn with the recitation of independent Claim 1, it is clear that dependent Claims 5-6 are likewise patentable over Tearney et al.

Independent Claim 12 recites: Apparatus for detecting neovascular flow through an obstruction in a blood vessel, said apparatus comprising a guide wire having a first proximal end and second distal end with at least one interferometric guidance system coupled thereto a guide wire, said guide wire distal end comprises at least one stationary optical fiber of said interferometric guidance system, a broad band filter coupled to an output of an interferometric apparatus, said interferometric apparatus generating interferometric peaks of varying frequencies; and a frequency-to-voltage converter coupled in series to said broad band filter. Applicant's claimed apparatus is not taught or suggested in Tearney et al. In particular Tearney et al. fails to teach or suggest a guide wire having a distal end comprising at least one stationary fiber as Applicants Claim 12 calls for. Thus independent Claim 12 is patentable over Tearney et al.

There is nothing in Tearney et al. which teaches or suggests the claimed invention or provides any motivation to somehow or in some way to change or modify Tearney et al. There is no suggestion in Tearney et al. to change, modify, what to change or if Tearney et al. were somehow changed for some reason that any resulting beneficial embodiment would occur. Moreover, even if Tearney et al were modified for some unknown reason Applicants claimed invention would not result. Moreover, even if Tearney et al. were somehow modified Applicants' claimed invention would not result in that Applicants claimed feature of a guide wire with an optical fiber forming its distal end is not taught nor suggested by Izatt et al.

Claim 13 depends on Claim 12. When the recitation of Claim 13 is combined with the recitation of Claim 12, it is clear that Claim 13 is likewise patentable.

There is nothing in Peterson et al. which describes the claimed invention in particular Applicants apparatus having a guide wire as called for in independent Claim 1 and independent Claim 12. Thus Claim 1 and Claim 12 are patentable over Peterson et al. Claims 5-6 are ultimately dependent on Claim 1. When the recitations of dependent Claims 5

and 6 are considered in combination with the recitation of Claim 2 and ultimately independent Claim 1, it is clear that dependent Claims 5-6 are likewise patentable over Peterson et al. Accordingly Claims 5-6 are patentable over Peterson et al. Claim 13 depends on Claim 12. When the recitation of dependent Claim 13 is taken into consideration with the recitation of independent Claim 12 it is clear that dependent Claim 13 is likewise patentable over Peterson et al. Moreover even if Peterson et al. were somehow modified Applicants' claimed invention would not result in that Applicants claimed feature of a guide wire with an optical fiber forming its distal end is not taught nor suggested by Peterson et al.

The Examiner has somehow combined Tearney et al. with Peterson et al. This combination of Tearney et al. with Peterson et al. is not permissible. There is nothing in either Tearney et al. or Peterson et al., which would motivate or provide a reason (nor has the Examiner provided a sustainable reason) for somehow combining these two references. Furthermore, even if the Examiner's asserted combinations were somehow made, Applicant's claimed invention would not result. Thus, the Examiner's combination cannot be sustained and should be withdrawn.

Claims 15-17 stand rejected under 35 USC 103(a) over Izatt et al in view of Swanson et al. This rejection is respectively traversed.

Applicants have previously shown that Applicant's independent Claim 14 is patentable over Izatt et al. Claims 15-17 depend directly or indirectly on Claim 14. When the recitations of Claims 15-17 are considered with the recitations of Claim 1, Applicants submit that dependent Claims 15-17 are likewise patentable over Izatt et al.

Swanson et al. discloses a method of imaging and scanning and obtaining information. In contrast Applicants' invention is a guidance apparatus (emphasis added). Further Applicants' claimed invention is configured using a guide wire having a distal end comprising at least one stationary fiber of an interferometric system and is configured to detect neovascular flow in tissue and the velocity of blood. Applicants' claimed elements are absent in Swanson et al. (emphasis added).

Further, Swanson et al. describes a method to compensate for varying Doppler shift induced by the method that is used to change the optical path length in the Swanson et al. device. In the previous paragraph to the citing (look at column 9, line 1), Swanson et al. describes a sinusoidal motion of mirror 32. The Doppler shift is directly proportional to a change in velocity ( $2V/\lambda$ ) and since the motion is sinusoidal, the velocity varies as a sine function. What is being described in Swanson et al. is a method to adjust the demodulator component to compensate for this varying Doppler shift caused by the sinusoidal velocity component. Applicant wishes to emphasize that the instant application provides a method to measure the velocity component of the sample, not to compensate for a varying velocity component in the reference. (The present invention uses linear changes in the path length so that the velocity component of path length change is constant and thus the observed variance is from the velocity change of the sample component.) Thus the claimed invention is patentable over Swanson.

The Examiner has somehow combined Izatt et al. with Swanson et al. The combination of Izatt et al. with Swanson et al. is not permissible. There is nothing in either Izatt et al. or Swanson et al. which would motivate or somehow provide a reason (nor has the Examiner provided a sustainable reason) for somehow combining the teaching of Izatt et al. and Swanson et al. Thus, the Examiner's combination of Izatt et al. with Swanson et al. cannot be sustained and must be withdrawn as that combination is improper. Applicants respectfully submit that it would not be obvious to one skilled in the art to combine Izatt et al. with Swanson et al. because there is no motivation to combine Izatt et al. with Swanson et al. As the Federal Circuit has recognized, obviousness is not established merely by combining references having different individual elements of pending claims. Ex parte Levensgood, 28 U.S.P.Q.2d (Bd. Pat. App. & Inter. 1993) MPEP 2143.01. Rather there must be some suggestions, outside of Applicants' disclosure in the art to combine such references. See in re Vaack, 20 U.S.P.Q. 2d 1435 (Fed. Ct. 1991). Applicants' submit that the office action fails to provide any prior art references that suggest adding together elements of the instant claims. Thus the combination of Izatt et al. with Swanson et al. is overcome and should be withdrawn.

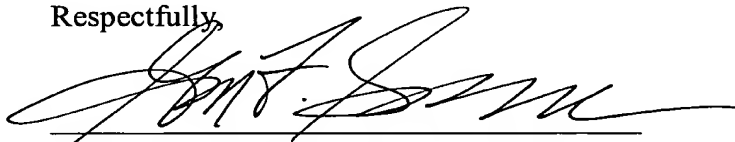
Additionally, the impermissible combination of Izatt et al. with Swanson et al. fails to teach and suggest the claimed invention in that Applicants' apparatus is a guidance apparatus comprising a guide wire having a distal end comprising at least one stationary fiber of an interferometric system configured to detect neovascular flow. In fact none of the cited references either alone or even in impermissible combinations cited by the Examiner teach or suggest Applicants' claimed invention. Specifically, the cited references fail to teach or suggest a guide wire having a distal end comprising at least one stationary fiber with an interferometric system coupled thereto. So even if the Examiner's combination were somehow made, the claimed invention would not result. Thus, this rejection is overcome and should be withdrawn.

The patentability of each dependent claim on its own merits is respectfully requested since each dependent claim is also deemed to define an additional aspect of the invention requiring consideration or reconsideration, as the case may be. All rejections have been traversed and overcome and are requested to be withdrawn.

All pending claims are patentable for at least the reasons put forth by Applicants above. The elements called for in the pending claims are not taught or suggested in the references asserted by the Examiner and thus all the independent and dependent claims are patentable.

In view of the foregoing remarks, all claims now active in this application are believed to be in condition for allowance. Reconsideration is requested along with early passage to issue. Favorable action and allowance are respectfully solicited. Kindly enter this amendment into the record of this application.

Respectfully,



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